

# 10th Meeting of the European Forum on Antiphospholipid Antibodies.

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**Title:** INSPIRE: the first Italian inception cohort of subjects positive for anti-phospholipid antibodies

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**Background:** Epidemiological and methodological data about testing for antiphospholipid antibodies (aPL) in general laboratories in Italy are lacking.

**Objectives:** FIRMA (Forum Interdisciplinare per la Ricerca nelle Malattie Autoimmuni), the Italian branch of EASI founded in the 90s and devoted to research in autoantibody field, is promoting a national prospective study, named INSPIRE (Italian Survey on Antiphospholipid antibody positive individuals [aPL Register]), which will be the first Italian inception cohort of aPL-positive individuals.

**Methods:** Subjects will be recruited when testing positive for the first time ever for one or more criteria aPL tests (anti-cardiolipin and anti- $\beta$ 2GPI IgG/IgM, lupus anticoagulant), at any titre. Patients with previously known aPL positivity will not be eligible for study inclusion. Blood will be drawn 12 weeks after the first sampling to confirm autoantibody positivity; aPL tests will be repeated in a single core laboratory for confirmation. Demographic and clinical data (thrombosis, pregnancy complications, non-criteria clinical manifestations, systemic autoimmune disease, cardiovascular risk-factors, treatment) will be entered in a web-based REDCap registry. The study will last 3 years (one year of enrolment; two years of follow-up).

**Results:** At least 10 FIRMA centres will participate with a minimum number of 30 enrolled subjects per centre, yielding to a study cohort of 300-400 aPL positive patients. INSPIRE will allow to: i) quantify aPL positivity rate in Italian laboratories; ii) assess the frequency of positive aPL confirmed at 12 weeks; iii) evaluate the clinical reasons for aPL testing; iv) collect data on aPL testing (reagents, techniques, reference ranges), estimating the reliability of results between different Italian laboratories; v) acquire demographic and clinical follow-up data in the first year(s) after aPL-positivity.

**Conclusions:** INSPIRE, an Italian inception cohort of aPL-positive subjects, will allow to collect evidence on several, still unravelled, clinical and methodological aspects of "real life" aPL testing.